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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,257	04/27/2007	Nobukazu Tanaka	286669US0PCT	2219

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

MILLIGAN, ADAM C

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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08/09/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/576,257	Applicant(s) TANAKA ET AL.	
	Examiner ADAM MILLIGAN	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 5/13/2010, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-12 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike (WO 02/30400 - See IDS dated 4/17/2006 – References contained herein are to English equivalent document U.S. 2004/0033258) in view of Masaki (U.S. 5,466,464).

Koike is discussed in the Office Action dated 11/13/2009 and incorporated herein by reference. Koike does not teach an embodiment having the ratio of mannitol to other saccharides in the range of (98-75):(2-25), as required by the newly presented claim amendments.

Masaki teaches that variation in the ratio of mannitol to lactose varied the disintegration time in orally disintegrating tablets (See tables 1 and 6). Masaki teaches using ratios of mannitol to lactose of 0:100, 20:80, 40:60, 60:40, and 100:0 (Table 6).

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Masaki did not teach the presence of an inorganic excipient from 1 to 30 parts by weight.

It would have been obvious to one of ordinary skill in the art to optimize the ratio of mannitol to lactose in the tablet rendered obvious by the primary reference in order to minimize the disintegration time as taught by the secondary reference.

With regard to the previous rejection based on Koike alone, Applicants assert that the Koike fails to disclose or suggest the ratio of mannitol to other saccharide(s) of (98-75):(2-25), as now amended and as such, Koike fails to render obvious the present invention. Applicants also assert that even assuming that sufficient motivation and guidance is considered present in the reference to arrive at the claimed weight ratio of mannitol to other saccharides, such a case of obviousness is rebutted by a showing of superior properties.

Examiner disagrees. The Masaki reference fulfills the asserted deficiency of Koike as discussed above.

With regard to the asserted unexpected results, the experiment appears to be designed with varying tablet pressure (See Table A). The data provided by Applicants demonstrates the disintegration times of tablets having various ratios of mannitol to lactose as well as indicates whether tableting troubles exist for the respective formulations. While the results do seem to indicate that the tablets having (98-75)% mannitol to (2-25)% lactose exhibit low disintegration times and do not result in tableting troubles, it is noted that another factor, tableting pressure, is present which is varied throughout the trials. The varying tableting pressure is reasonably expected to

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effect the oral disintegration time as well, considering the compression will likely effect the moisture penetration into the fillers. Thus, it is unclear whether it is truly the instantly claimed sugar ratio or the varying tablet pressure which is responsible for the results obtained.

Further, based on teaching of the secondary reference, disintegration times vary where the ratio of mannitol to lactose are varied. As such, variance in disintegration times presented in Table A of the instant declaration are not necessarily unexpected.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koike (WO 02/30400 - See IDS dated 4/17/2006 – References contained herein are to english equivalent document U.S. 2004/0033258) in view of Masaki (U.S. 5,466,464), The combination further in view of Ishikawa (Preparation of Rapidly Disintegrating Tablet Using New Types of Microcrystalline Cellulose (PH-M Series) and Low Substituted-Hydroxypropylcellulose or Spherical Sugar Granules by Direct Compression Method, Chem. Pharm. Bull., Vol.49, No.2, pp.134-139, 2001).

Applicants assert Koike fails to make a prima facie case of obviousness and Ishikawa fails to remedy the shortcomings.

Examiner disagrees. As discussed above, Koike in view of Masaki provides a prima facie case of obviousness over the amended claims. As Applicants have failed to present arguments with regard to Ishikawa specifically, the addition of Ishikawa is proper for rejection claim 13.

Nonstatutory Double Patenting

The basis for nonstatutory double patenting not included in this action can be found in a prior Office Action.

Claims 1-13 and 16-19 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-28, and 30-32 of copending Application No. 10/945,049.

Applicants request this rejection be held in abeyance until allowable subject matter is indicated. .

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

/ADAM MILLIGAN/
Examiner, Art Unit 1612